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TRANSMITTAL OF APPEAL BRIEF (Large Entity)	Docket No. PA0071

In Re Application Of: **Michael Alan Reeve**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/007,327	November 8, 2001	Pensee T. Do	22840	1641	3254

Invention: **Separation Particles**

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **October 28, 2005**

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Royal N Ronning Jr
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Dated: **December 14, 2005**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/007,327	Confirmation No.: 3254
Applicant	:	Michael Alan Reeve	
Filed	:	November 8, 2001	
TC/A.U.	:	1641	
Examiner	:	Pensee T. Do	
Docket No.	:	PA0071	
Customer No.	:	22840	

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Alexandria, Virginia 22313-1450

December 14, 2005

APPEAL BRIEF

Sir:

Appellant submits this Appeal Brief in triplicate, appealing from the July 26, 2005, rejection of the Primary Examiner, finally rejecting claims 1–3, in the captioned application. The Notice of Appeal was filed on October 28, 2005, which contained authorization to charge the "Appeal Fee" to Appellant's Deposit Account. Filed concurrently herewith is the "Transmittal of Appeal Brief (Large Entity)", in duplicate, which contains authorization to charge the fee for filing the Appeal Brief to Appellant's Deposit Account.

Real Party in Interest

Amersham PLC, the assignee and owner of the captioned application, is the real party in interest to this appeal.

Related Appeals and Interferences

There are no other appeals or interferences related to the instant appeal.

Status of Claims

Claims 1–16 are pending in the captioned application. Claims 4–16 have been withdrawn from consideration as being directed to an unelected invention; hence, claims 1–3 are the claims subject to examination before the U.S. Patent and Trademark Office. A copy of these claims is appended hereto.

Status of Amendments

There are no outstanding amendments with regard to the captioned application.

Summary of Claimed Subject Matter

The instant invention relates to a composition comprising colloidal Fe_3O_4 particles coated with streptavidin is disclosed. These particles can be used in a method for separating biotinylated compounds from a solution in which the biotinylated compounds bind to the streptavidin-coated particles which are attracted to a surface by a magnet.

Also disclosed is a method for making said streptavidin-coated composition, said method comprising the steps of forming colloidal Fe_3O_4 particles by mixing aqueous $FeCl_2$ with aqueous $FeCl_3$, adding aliquots of the mixture to an alkaline solution and adding streptavidin (see e.g., the Abstract).

Claims are directed to the particles coated with a biotin-binding protein (claim 1) and recite the biotin-binding protein as being avidin (claim 2)or streptavidin (claim, 3). This is disclosed *inter alia* at page 1, lines 9–25.

Grounds of Rejection to be Reviewed on Appeal

1. Whether claims 1–2 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Owen, et al. (US 4,795,698).
2. Whether claims 1–3 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Ekenberg (US 5,693,784).
3. Whether claims 1–3 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rao, et al. (US 5,660,990).
4. Whether claims 1–3 are properly rejected under 35 U.S.C. § 102(e) as being anticipated by Terstappen (US 6,228,624).

Argument

1. Claims 1–2 are not properly rejected under 35 U.S.C. § 102(b) as being anticipated by Owen, et al. (US 4,795,698).

The Examiner has rejected claims under 35 U.S.C. § 102(b) as "being anticipated by Owen et al. (US 4,795,698)".

Specifically, the Examiner stated, "Owen teaches magnetic-polymer particles wherein the magnetic particles are magnetite (Fe3O4). Such magnetic polymer particles are coated with avidin..."

In response, Appellant asserted that the Examiner had mischaracterized the instant invention. Specifically, as stated at pages 3–4, the instant invention provides compositions comprising colloidal Fe_3O_4 particles coated with a biotin-binding protein. The particles themselves are coated with the biotin-binding protein without the need for additional coatings, resulting in particles which have a very high iron content. This aids the speed and efficiency of magnetic separations.

In contrast, in the methodology provided by Owen, et al. the magnetic particles are formed by combining iron oxide in solution with a polymer (such as a protein) (see col. 3, lines 25–35). These coated particles are disclosed as capable of being "tailor-made to include specific biofunctional ligands useful in various...applications" (see col. 3, lines 58–61). As such, the particles are quite different from those of the instant invention.

Further, Appellant amended claim 1 to recite that the composition "consists essentially of the particles coated with the biotin-binding protein", noting that such is neither disclosed nor even suggested by Owen, et al.

In response to this argument, the Examiner states, "Applicants have amended the claims to recite 'a composition consisting essentially of...' and argued that the references cited in the previous office action are irrelevant to the amended claims. The composition in the references cited by the examiner contains an additional polymer coating whereas the present invention does not. The language 'consisting essentially of ' fails to exclude all the extraneous materials in a composition. MPEP 2111.03 [R-2] states that 'For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of will be construed as equivalent to 'comprising.' See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ('PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention'"

The Examiner continues, "The additional polymer coating fails to affect the basic and novel characteristics of the present invention because such a coating is well known in the art for providing functional groups to immobilize the affinity ligand such as a streptavidin or avidin. Therefore, the references applied in the previous office action are still relevant to the claims as presented".

In response, Appellant respectfully submits that the Examiner has improperly construed the language of the claims. Specifically, as disclosed in the specification and raised in the argument presented above, the instant invention provides compositions comprising colloidal Fe_3O_4 particles coated with a biotin-binding protein. Since the particles themselves are coated with biotin-binding proteins **without the need for additional coatings**, the resulting particles have a very high iron content, which aids the speed and efficiencies of magnetic separations. Quite the contrary, the magnetic particles of Owen, et al. are formed by combining iron oxide in solution with a polymer and then these coated particles are disclosed as being capable of being "tailor-made to include specific biofunctional ligands useful in various...applications" (see col. 4, lines 59–61). As such, the particles of Owen, et al. are quite different because they contain other polymers and, as such, will have different properties.

While Appellant is mindful that the phrase "consisting essentially of" will exclude only elements which will affect the basic and novel characteristics of the invention, Appellant respectfully asserts that that is precisely what would occur here. Specifically, because the particles of Owen, et al. cannot have as high an iron content as that of the instant invention by virtue of the fact that Owen, et al. includes a polymer coating, Appellant respectfully asserts that the properties of the particles disclosed by Owen, et al. will be quite different from those of the instant invention and specifically, will not have the novel characteristics conferred by the higher iron content of the particles of the instant invention.

Accordingly, Appellant respectfully submits that the language "consisting essentially of" contained within the claims adequately responds to the Examiner's' rejection.

In view of the foregoing, Appellant respectfully submits that the Examiner's rejection cannot be sustained and should be reversed.

2. Claims 1–3 are not properly rejected under 35 U.S.C. § 102(b) as being anticipated by Ekenberg (US 5,693,784).

The Examiner has rejected claims 1–3 under 35 U.S.C. § 102(b) as "being anticipated by Ekenberg (US 5,693,784)".

Specifically, the Examiner stated, "Ekenberg teaches an agglomeration of colloidal magnetic particles coated with streptavidin. The magnetic particles are metal oxides (Fe304)..."

In response, Appellant reiterated the arguments as to the inapplicability of the Owens, et al. reference, and respectfully asserted that the Ekenberg reference does not teach direct coating. More specifically, the reference discloses that "The paramagnetic particles may be provided with a nonmagnetic polymeric matrix or coating" (see col. 4,

lines 66–67), and discloses particles available from Advanced Magnetic Corporations as useful products in the processes of the invention disclosed (see col. 5, lines 10–23).

Such particles generally comprise silanized particles, i.e. particles treated with silane to facilitate the bonding of the ligands (see e.g. US 4,695,393). Further, example 8 discloses particles made by the method of Owen, et al. Thus, Appellant respectfully submitted that while the references neither disclose nor enable the particles of this invention.

While the Examiner did not respond directly to this argument, it appears that the Examiner intended for the argument against the term "consisting essentially of" to be directed to this rejection, as well.

In response, Appellant respectfully reasserts the arguments presented above as to the reason the basic and novel characteristics of the invention will be changed by the including of a polymeric coating such as the silanized coating taught by Ekenberg, and respectfully submits that particles disclosed by Ekenberg neither discloses nor even suggests the instant invention.

In view of the foregoing, Appellant respectfully submits that the Examiner's rejection cannot be sustained and should be reversed.

3. Claims 1–3 are not properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rao, et al. (US 5,660,990).

The Examiner has rejected claims 1–3 under 35 U.S.C. § 102(b) as "being anticipated by Rao (US 5,660,990)".

Specifically, the Examiner stated, "Rao teaches magnetic particles coated with avidin or streptavidin. Magnetic particles behave as colloids and are prepared according to the methods of Owen (US 4,795,698). These particles are Fe3O4..."

In response, Appellant reiterated the arguments as to the inapplicability of the rejection in view of Owen, et al., and pointed out that the patent states that the magnetic particles having their desirable properties "can be prepared as described in U.S. Pat. No. 4,795,698," (see col. 9 lines 1–2). Because the same methodology is utilized, Appellant respectfully asserted that the particles prepared will be those of Owen, et al., and, thus, that the Rao, et al. reference neither discloses nor even suggests the particles of the instant invention.

In response, again, the Examiner did not specifically address this argument, but apparently intended the discussion of the term "consisting essentially of" to be applied to this argument, as well.

In response, Appellant respectfully reiterates the arguments presented above as to the reason the term "consisting essentially of" excludes the particles of Owen, et al. and respectfully submits that because the methodology disclosed by Rao, et al. is the same as that of Owen, et al., these particles will be produced.

Accordingly, Appellant respectfully asserts that the Rao, et al. reference neither discloses nor even suggests the instant invention.

In view of the foregoing, Appellant respectfully submits that the Examiner's rejection cannot be sustained and should be reversed.

4. Claims 1–3 are not properly rejected under 35 U.S.C. § 102(e) as being anticipated by Terstappen (US 6,228,624).

The Examiner has rejected claims 1–3 under 35 U.S.C. § 102(e) as "being anticipated by Terstappen (US 6,228,624)".

Specifically, the Examiner stated, "Terstappen teaches using magnetic particles prepared by methods in US patent 4,795,698 by Owen wherein Owen teaches preparation of magnetic particles by using solution containing Fe(II) and Fe(III) and a polymer treated with a strong base in order to precipitate magnetic iron oxides such as magnetite (Fe304) in a form which in intimately combined with the polymer. Such magnetic particles are coated with avidin or streptavidin..."

The Appellant responded to this rejection, maintaining that such response should not be taken as an acquiescence that the Terstappen patent is properly prior art against the instant invention. Nevertheless, as the Examiner has admitted, the particles are prepared by methods in U.S. 4, 795, 698 (Owen, et al.) and as such neither discloses nor even suggests the particles of the instant invention.

In response, the Examiner did not specifically address this argument, but apparently intended the discussion of the term "consisting essentially of" to be applied in response to this argument, as well.

In response, Appellant respectfully asserts the arguments presented above as to the reason the language "consisting essentially of" does not include the particles of Owen, et al. and respectfully asserts that because the particles of Terstappen are prepared by the same method of Owen, et al., the particles will be the same.

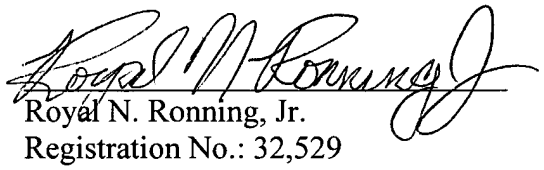
Accordingly, Appellant respectfully asserts that the Terstappen reference neither discloses nor even suggests the instant invention.

In view of the foregoing, Appellant respectfully submits that the Examiner's rejection cannot be sustained and should be reversed.

Conclusion

In view of the foregoing arguments, Appellant respectfully asserts that the Examiner's rejections cannot be sustained, and should be reversed.

Respectfully submitted,



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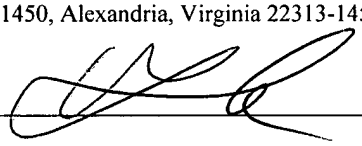
Signature: 

Name: Melissa Leck

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CLAIMS APPENDIX

The Rejected Claims

Claim 1 (previously presented): A composition consisting essentially of colloidal Fe_3O_4 particles coated with a biotin-binding protein.

Claim 2 (previously presented): The composition of claim 1, wherein the biotin-binding protein is avidin or streptavidin.

Claim 3 (previously presented): The composition of claim 2, wherein the biotin-binding protein is streptavidin.

Claim 4 (withdrawn): A method for synthesis of a composition as claimed in claim 3, said method comprising the steps of incubating colloidal Fe_3O_4 particles with a biotin-binding protein.

Claim 5 (withdrawn): A method as claimed in claim 4, further comprising the steps of:

a) forming colloidal Fe_3O_4 particles by mixing aqueous $FeCl_2$ with aqueous $FeCl_3$ and adding aliquots of the mixture to an alkaline solution;

b) adding a biotin-binding protein.

Claim 6 (withdrawn): A method as claimed in claim 5, wherein the molar ratio of $FeCl_2$: $FeCl_3$ is between 1:1.5 and 1:2.

Claim 7 (withdrawn): A method as claimed in claim 6, wherein the molar ratio of $FeCl_2$: $FeCl_3$ is 1:1.5.

Claim 8 (withdrawn): A method as claimed in claim 7, wherein the aqueous $FeCl_2$ is $FeCl_2.4H_20$.

Claim 9 (withdrawn): A method as claimed in claim 8, wherein the aqueous $FeCl_3$ is $FeCl_3.6H_2O$.

Claim 10 (withdrawn): A method as claimed in claim 9, wherein said forming step further includes adding an ammonia solution to the mixture of $FeCl_2$ and $FeCl_3$.

Claim 11 (withdrawn): A method as claimed in claim 10, wherein the biotin-binding protein is added in excess.

Claim 12 (withdrawn): A method as claimed in claim 11, wherein the biotin-binding protein is streptavidin.

Claim 13 (withdrawn): A method of immobilising a biotinylated compound comprising incubating said biotinylated compound in solution in the presence of a composition as claimed in claim 1.

Claim 14 (withdrawn): A method as claimed in claim 13, wherein the biotinylated compound is selected from the group consisting of a nucleic acid molecule, a protein, and a peptide.

Claim 15 (withdrawn): A method as claimed in claim 14, further comprising the step of separating the biotinylated compound and the composition from said solution.

Claim 16 (withdrawn): A method as claimed in claim 15, wherein said separating step further comprises the step of magnetically attracting the biotinylated compound and the composition to a surface.

EVIDENCE APPENDIX

Appellant hereby appends copies of the following:

1. U.S. Patent 4,795,698 to Owen, et al.;
2. U.S. Patent 5,693,784 to Ekenberg;
3. U.S. Patent 5,660,990 to Rao, et al.; and
4. U.S. Patent 6,228,624 to Terstappen.

This is the evidence relied upon by the Examiner for rejection of appealed claims.